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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,576	10/20/2003	Dario Renato Alessi	002.00022 (MEDY/P17930US)	8451
7590 Karla M. Weyand Rogalskyj & Weyand, LLP PO Box 44 Livonia, NY 14487-0044			03/06/2007 EXAMINER RAMIREZ, DELIA M	
			ART UNIT 1652	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/06/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/689,576	Applicant(s) ALESSI, DARIO RENATO	
	Examiner Delia M. Ramirez	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-16 and 18-35 is/are pending in the application.
- 4a) Of the above claim(s) 10-16,18-27,29 and 33-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9,28,30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/943,667.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. attached to This
- 5) ☐ Notice of Informal Patent Application Office
- 6) ☐ Other: _____ Action 2/22/07

DETAILED ACTION

Status of the Application

Claims 1-3, 5-16, 18-35 are pending.

Applicant's amendment of claims 1-3, 28, 30-32, 34-35, and cancellation of claims 4 and 17 as submitted in a communication filed on 12/13/2006 is acknowledged.

Applicant's amendment of the specification which adds sequence identifiers and a new title as submitted in a communication filed on 12/13/2006 is acknowledged.

As indicated in previous Office action mailed on 7/13/2006, claims 10-16, 18-27, 29, 33-35 were withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-3, 5-9, 28, 30-32 are at issue and are being examined herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Terminal Disclaimer

1. The terminal disclaimer filed on 12/13/2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6734001 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112, Second Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1-2, 5-9, 28, 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is a new rejection necessitated by amendment.

4. Claims 1 and 31 (claims 2, 5-9, 28, 30, 32 dependent thereon) are indefinite in the recitation of "rabbit 3-phosphoinositide-dependent protein kinase.....wherein the protein kinase comprises amino acids 83 to 342 of SEQ ID NO: 1" and "protein kinase according to claim 1 wherein the protein kinase comprises amino acids 52-556 of SEQ ID NO: 1 or amino acids 52-556 of SEQ ID NO: 1 with from 1 to 4 conservative amino substitutions..." for the following reasons. While it is clear to the Examiner that the intended protein kinase is a rabbit protein kinase having the recited structural characteristics, based on the teachings of the specification and the knowledge of one of ordinary skill in the art, it is unlikely that the recited protein kinase exists. The polypeptide of SEQ ID NO: 1 has been disclosed in the specification as a human protein kinase. The claims require large fragments of the human polypeptide of SEQ ID NO: 1 to be present in a rabbit protein (fragments are 206, 101 and 505 amino acids long) The specification does not teach that the rabbit protein kinase of the invention comprises the recited fragments. While one of skill in the art would expect a high degree of structural similarity between the human and rabbit protein kinases disclosed in the specification, in the absence of evidence to the contrary, one of skill in the art would not necessarily expect the rabbit protein kinase of the invention to comprise the large fragments of SEQ ID NO: 1 as recited. If Applicant provides evidence indicating that there is a rabbit protein kinase having the recited functional characteristics which comprises the recited fragments of SEQ ID NO: 1, this rejection will be withdrawn. Correction/clarification is required.

Claim Rejections - 35 USC § 112, First Paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3, 5-9, 28, 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection necessitated by amendment.

Claims 1-2, 5-9, 28, 30 require in part a genus of rabbit 3-phosphoinositide protein kinases that comprise amino acids 83-342 and 450-550 of SEQ ID NO: 1. Claim 3 is directed to a genus of 3-phosphoinositide-dependent protein kinases that comprise SEQ ID NO: 1 with from 2 to 4 conservative amino acid substitutions. Claims 31-32 are directed in part to a genus of rabbit 3-phosphoinositide-dependent protein kinases that comprise amino acids 52-556 of SEQ ID NO: 1, or comprise amino acids 52-556 of SEQ ID NO: 1 with from 1 to 4 conservative amino acid substitutions.

While the Examiner has been able to find support for a human 3-phosphoinositide-dependent protein kinase comprising (a) amino acids 83-342 and 450-550 of SEQ ID NO: 1, or (b) amino acids 52-556 of SEQ ID NO: 1, the Examiner is unable to find support for a rabbit 3-phosphoinositide-dependent protein kinase comprising amino acids 83-342 and 450-550 of SEQ ID NO: 1, or amino acids 52-556 of SEQ ID NO: 1. In addition, while the Examiner has been able to find support for a genus of variants of the polypeptide of SEQ ID NO: 1, wherein said variants comprise SEQ ID NO: 1 with from 1 to 4 conservative substitutions, the Examiner is unable to find support for variants of the polypeptide of SEQ ID NO: 1, wherein said variants comprise SEQ ID NO: 1 with 2 to 4 conservative amino acid substitutions. Thus there is no indication that the proteins recited in the claims were within the scope of the invention as conceived by Applicants at the time the application was filed. Accordingly, Applicant is required to cancel the new matter in the response to this Office Action.

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-2, 4-9, 17, 28, 30 were rejected under 35 U.S.C. 102(a) as being anticipated by Alessi et al. (Current Biology 7(4):261-269, April 1997; cited in the IDS). This rejection has been discussed at length in the Non Final action mailed on 7/13/2006.

9. Claims 4 and 17 have been cancelled. Claims 1-2, 5-9, 28 and 30 now require a rabbit protein kinase which comprises amino acids 83-342 and 450-550 of SEQ ID NO: 1. Alessi et al. disclose a rabbit 3-phosphoinositide-dependent protein kinase which meets all the functional limitations recited and is isolated from rabbit skeletal muscle. However, the claims now require the rabbit protein kinase to comprise a 260-amino acid fragment and a 101-amino acid fragment of SEQ ID NO: 1. The polypeptide of SEQ ID NO: 1 has been disclosed as a human protein kinase. As indicated above in the 35 USC 112, first and second paragraph rejections, there is no evidence in the specification that the rabbit protein kinase of the instant application comprises large fragments found in the human protein kinase of SEQ ID NO: 1. While one of skill in the art can reasonably expect a high degree of structural similarity between the human and rabbit protein kinases, in the absence of evidence to the contrary, one of skill in the art would not necessarily expect the rabbit protein kinase to comprise 260- and 101-amino acid fragments of the human protein kinase. Since Alessi et al. do not teach the sequence of the rabbit protein kinase and the specification of the instant application does not disclose the rabbit protein kinase as having the recited fragments of SEQ ID NO: 1, this rejection is hereby withdrawn. It is noted, however, that if evidence is presented showing that the rabbit protein kinase of the invention comprises the recited fragments, this rejection may be reintroduced.

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10. Claim 17 was rejected under 35 U.S.C. 102(b) as being anticipated by Dietrich, F.S. (PIR accession number S69657, 1996).

11. In view of Applicant's cancellation of claim 17, this rejection is hereby withdrawn.

Double Patenting

12. Claims 1-9, 17, 28, 30-32 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, 14 of U.S. Patent No. 6734001.

13. In view of Applicant's submission of a terminal disclaimer disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6734001, this rejection is hereby withdrawn.

Conclusion

14. No claim is in condition for allowance.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.
Primary Patent Examiner
Art Unit 1652

DR
February 23, 2007